

## **REMARKS**

### **Status of the Claims**

Claims 1-4 are pending in the application. Claims 1 and 2 are presently withdrawn due to a restriction requirement. Claim 3 is currently amended. Reconsideration and allowance of all of the pending claims is respectfully requested.

This amendment does not add new matter to the application as filed. The amendment to claim 3 is supported at page 10, line 4 to page 11, line 8 of the specification, and at page 16, first full paragraph, and also by Example 1. Accordingly, no new matter is added and entry of this amendment is respectfully requested.

### **Claim Rejections – 35 U.S.C. §102/§103**

Claims 3 and 4 are rejected under 35 U.S.C. §102(b) as anticipated by Jennings '710 (WO 00/13710). Claims 3 and 4 are also rejected under 35 U.S.C. §102(e) as being anticipated by Komeda '738 (U.S. Patent No. 6,732,738). Claims 3 and 4 are rejected under 35 U.S.C. §103(a) as being unpatentable over Jennings '710 in view of Ikada '058 (U.S. 6,831,058). Applicants respectfully traverse each of these rejections for the following reasons.

#### *1. The Present Invention*

The present invention relates to a method for treating coronary artery narrowing or blockage comprising administering a sustained release preparation containing an angiogenesis factor which is complexed with a gelatin hydrogel. Claim 3 recites that the gelatin hydrogel is crosslinked before being complexed with the angiogenesis factor. Crosslinking the gelatin

enables sustained release of angiogenesis factors over a long period of time. The present specification discloses that the present invention permits the sustained release of a growth factor for two weeks. See e.g., Example 2, page 23.

## *2. Distinctions between the present invention and the prior art*

### A. Jennings '710

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Applicants respectfully submit that Jennings '710 does not expressly or inherently disclose a hydrogel which is crosslinked as recited in claim 3. Accordingly each and every element of the present invention is not disclosed by Jennings '710 and this rejection should be withdrawn.

Jennings '710 discloses a hydrogel which, because it is not crosslinked, can only provide a slow-release of drugs for several hours. This time period is not long enough to treat the cardiac diseases recited in claim 3. This is shown by, for example, the data of Figures 5 and 6 of Jennings '710. Accordingly, Jennings '710 does not disclose all of the elements of the present invention and this rejection must be withdrawn.

### B. Komeda '738

The Examiner asserts that Komeda '738 discloses a method for treating cardiovascular disease by the administration of a gelatin hydrogel containing bFGF. However, applicants

respectfully submit that this is not the case. Komeda '738 merely mentions in the Background section that bFGF has the benefit of enhancing sternal healing via angiogenic effects.

However, Komeda '738 does not expressly or inherently disclose methods of treating coronary artery narrowing or blockage using a crosslinked gelatin hydrogel complexed with bFGF as presently recited in claim 3. Accordingly, Komeda '738 also does not disclose each and every element of the present invention, and this rejection should also be withdrawn. Withdrawal is respectfully requested.

*3. Jennings '710 in view of Ikada '058*

"To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art." MPEP §2143.03. Jennings '710 in view of Ikada '058 also fails to disclose a crosslinked hydrogel. Further, Ikada '058 fails to disclose or suggest applying bFGF-containing gelatin hydrogel to the treatment of cardiac diseases as presently claimed. One skilled in the art would not arrive at the invention of claim 3 by combining Jennings '710 and Ikada '058. Accordingly, applicants submit that a *prima facie* case of obviousness has not been established, and this rejection should be withdrawn.

Jennings '710 was discussed above and does not disclose or suggest a hydrogel which is crosslinked as recited in claim 3. Accordingly, applicants respectfully submit that all of the limitations of claim 3 are not disclosed or suggested by the prior art, and that this rejection should also be withdrawn for the same reasons as given above in regard to Jennings '710.

Furthermore, Ikada '058 mentions that bFGF may be slow released for inducing angiogenesis. However, Ikada '058 does not disclose or suggest to one of skill in the art all of the

elements of claim 3. Ikada '058 does not disclose or suggest methods for treating coronary artery narrowing or blockage as recited in the present claim 3. In particular, Ikada '058 does not disclose or suggest that their methods could be effective in treating the heart which is an actively moving organ.

The present invention is the first demonstration that crosslinked gelatin hydrogel containing bFGF can be retained in an actively moving organ such as the heart to allow for the slow release of angiogenesis factors over a long period of time. The present invention demonstrates a remarkable and unexpected therapeutic effect for the presently claimed methods using sustained release preparations to treat coronary artery narrowing or blockage.

Accordingly, all of the present claim limitations are not disclosed or suggested by the prior art. Applicants respectfully submit that this rejection should be withdrawn. An early reconsideration and Notice of Allowance are respectfully requested.

## **Conclusion**

In view of the above amendment, applicant believes the pending application is in condition for allowance.

In view of the above remarks, it is believed that claims are allowable.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact the undersigned at the telephone number listed below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

Application No. 10/528,998  
Amendment dated November 27, 2007  
Reply to Office Action of August 27, 2007

Docket No.: 3691-0119PUS1

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.14; particularly, extension of time fees.

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Respectfully submitted,

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